

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
WICHITA FALLS DIVISION**

**CHRISTOPHER S. BURCH,** §  
§  
**Plaintiff,** §  
§  
v. § **Civil Action No. 7:21-cv-00002-M-BP**  
§  
**KLS MARTIN, LP,** §  
§  
**Defendant.** §  
§

**FINDINGS, CONCLUSIONS, AND RECOMMENDATION  
OF THE UNITED STATES MAGISTRATE JUDGE**

Before the Court are Defendant KLS Martin, LP's Motion to Dismiss Plaintiff's First Amended Complaint; Plaintiff Christopher Burch's Response; and Defendant KLS Martin's Reply to that Response. ECF Nos. 18, 19, and 21, respectively. After considering the pleadings and applicable legal authorities, the undersigned **RECOMMENDS** that Chief United States District Judge Barbara M. G. Lynn **GRANT in part** and **DENY in part** Defendant KLS Martin's Motion to Dismiss Plaintiff's First Amended Complaint. ECF No. 18. The undersigned recommends that Chief Judge Lynn **GRANT** the Motion as to counts two, four, and five of the Amended Complaint (failure to warn and breach of warranty claims), but **DENY** the Motion as to counts one and three of the Amended Complaint (design and manufacturing defect claims).

**I. BACKGROUND**

This is a product liability case involving an allegedly defective thoracic plate designed and manufactured by KLS Martin, LP ("KLS"). On March 4, 2019, Dr. Shafi Mohamed performed a right-side thoracotomy on Christopher Burch ("Burch"), inserting the KLS plate between Burch's ninth and tenth right-side ribs. ECF No. 1 at 3-4. Burch heard a "popping" sound when he sneezed

in June 2019, and upon subsequent visits to his doctor he discovered the plate had fractured. *Id.*

Seeking damages from KLS for injuries allegedly sustained because of the broken plate, Burch alleges claims for design defect, failure to warn, manufacturing defect, breach of express warranty, and breach of the implied warranties of merchantability and fitness for a particular purpose. *Id.* at 4-8. KLS previously moved to dismiss all counts in Burch's Complaint, arguing that he failed to plead legally cognizable claims. ECF No. 7. Burch filed an Amended Complaint reiterating each count and clarifying grounds for KLS's alleged liability. ECF No. 13. With the Amended Complaint, Burch requested denial of KLS's Motion to Dismiss as moot. ECF No. 14. Thereafter, by Order dated May 25, 2021, the Court deemed the Motion to Dismiss (ECF No. 7) moot and ordered KLS to file an answer or other pleading or motion in response to the Amended Complaint. ECF No. 16.

KLS complied with that Order and again moved to dismiss Burch's claims. ECF No. 18. The Motion to Dismiss the Amended Complaint ("Motion") urges the Court to dismiss each count in Burch's Amended Complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. *Id.* Burch responded to the Motion, denying that the Amended Complaint failed to state a viable claim for relief and reiterating the grounds for relief in each count. ECF No. 19. KLS replied, arguing that Burch's claims were implausible and based on injuries that predated the insertion of any KLS medical device. ECF No. 21. KLS's reply pointed to Burch's medical records, which evidence "a pre-existing and continuing non-union of a rib fracture [Burch] sustained in the first half of 2018." *Id.* at 2 (citing ECF No. 19-1 at 21-22). KLS argues the plate fractured "[w]hen the non-union persisted as a result of the bone fragments' continued failure to consolidate through the graft material," not because of any design or manufacturing defect. *Id.*

After considering the arguments on each count, the undersigned finds that Burch alleges plausible design and manufacturing defect claims that Chief Judge Lynn should not dismiss under Rule 12(b)(6). However, Burch does not assert plausible failure to warn and breach of express or implied warranties claims, and Chief Judge Lynn should dismiss counts two, four, and five of the Amended Complaint under Rule 12(b)(6).

## II. LEGAL STANDARDS

### A. Rule 12(b)(6) Standard

Federal Rule of Civil Procedure 12(b)(6) permits dismissal of a complaint for “failure to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). To state a viable claim for relief, Rule 8 requires “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(1). While a complaint does not need detailed factual allegations to survive a Rule 12(b)(6) motion to dismiss, “a formulaic recitation of the elements of a cause of action will not do.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation omitted). Rather, the complaint must include enough facts “to raise a right to relief above the speculative level” with the court operating “on the assumption that all the complaint’s allegations are true.” *Id.*

District courts “can grant a motion to dismiss only if it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim that would entitle him to relief.” *Scanlan v. Tex. A&M Univ.*, 343 F.3d 533, 536 (5th Cir. 2003) (citing *Leffall v. Dall. Indep. Sch. Dist.*, 28 F.3d 521, 524 (5th Cir. 1994)). Thus, “[a] complaint is subject to dismissal for failure to state a claim if the allegations, taken as true, show the plaintiff is not entitled to relief.” *Jones v. Bock*, 549 U.S. 199, 215 (2007). When considering a Rule 12(b)(6) motion, courts must “take all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff . . . and ask whether

the pleadings contain ‘enough facts to state a claim to relief that is plausible on its face.’” *Yumilicious Franchise, LLC v. Barrie*, 819 F.3d 170, 174 (5th Cir. 2016) (quoting *Twombly*, 550 U.S. at 570). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556).

While plausibility is context-specific, this Court and the Fifth Circuit more broadly disfavor Rule 12(b)(6) dismissals unless the complaint’s insufficiency is self-evident. *See Scanlan*, 343 F.3d at 536; *Shaunfield v. Experian Info. Sols.*, 991 F. Supp. 2d 786, 793 (N.D. Tex. 2014). The 12(b)(6) analysis involves plausibility, which is distinct from probability or persuasiveness. *Iqbal*, 556 U.S. at 678. Thus, “Rule 12(b)(6) does not countenance . . . dismissals based on a judge’s disbelief of a complaint’s factual allegations.” *Neitzke v. Williams*, 490 U.S. 319, 327 (1989).

Because jurisdiction in this case is based on diversity of citizenship, Texas substantive law applies. *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938); *ACE Am. Ins. v. Freeport Welding & Fabricating, Inc.*, 699 F.3d 832, 839 (5th Cir. 2012). The parties do not disagree on this point.

## **B. Design Defect Standard**

To prevail on a design defect claim under Texas law, plaintiffs must prove three elements: “(1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury.” *Timpke Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009) (citations omitted). To determine if a product is “unreasonably dangerous,” Texas courts analyze five factors:

(1) The utility of the product to the user and to the public as a whole weighed against the gravity and likelihood of injury from its use; (2) the availability of a substitute product which would meet the same need and not be unsafe or unreasonably expensive; (3) the manufacturer’s ability to eliminate the unsafe character of the product without seriously impairing its usefulness or significantly increasing its costs; (4) the user’s anticipated awareness of the dangers inherent in the product

and their avoidability because of the general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions; [and] (5) the expectations of the ordinary consumer.

*Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 256 (Tex. 1999) (citing *Amer. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 432 (Tex. 1997)).

### **C. Manufacturing Defect Standard**

Texas law provides that “[a] manufacturing defect exists when a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous.” *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 600 (Tex. 2004) (citations omitted). To prevail on a manufacturing defect claim, plaintiffs must show that the product “was defective when it left the hands of the manufacturer and that the defect was a producing cause of the plaintiff’s injuries.” *Torrington Co. v. Stutzman*, 46 S.W.3d 829, 844 (Tex. 2000). Because the internal details of a business’s manufacturing processes are typically confidential, to require a more detailed showing at the 12(b)(6) stage would “make pleading a [] claim regarding defective manufacturing nearly impossible.” *Bass v. Stryker*, 669 F.3d 501, 511 (5th Cir. 2012).

### **D. Failure to Warn Standard**

When a warning is required, a defendant’s failure to warn of a product’s potential risks is considered a “marketing defect” under Texas law. *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 382 (Tex. 1995); *Lucas v. Tex. Indus., Inc.*, 696 S.W.2d 372, 377 (Tex. 1984). The existence of a duty to warn is a question of law. *Gen. Motors Corp. v. Saenz*, 873 S.W.2d 353, 356 (Tex. 1993). In circumstances where a warning is required but not given, or given inadequately, a “plaintiff must show both that the warning was defective and that it was the producing cause of the plaintiff’s injury.” *Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 94 (Tex. App.—Texarkana 2000, no pet.) (citation omitted).

The learned intermediary doctrine provides an exception to the duty to warn under Texas law in cases involving claims of defective medical devices. *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 467-68 (5th Cir. 1999) (citing *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591-92 (Tex. 1986)). The doctrine relaxes the warning obligation when a learned intermediary, like a physician, can weigh a product's costs and benefits and should thus bear responsibility for advising consumers accordingly. *See Reyes v. Wyeth-Ayerst Labs. Co.*, 498 F.2d 1264, 1276 (5th Cir. 1974); *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 795, 797 (E.D. Tex. 2002). When applicable, the doctrine excuses medical product manufacturers “from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product’s dangers.” *Porterfield*, 183 F.3d at 467-68 (citing *Alm*, 717 S.W.2d at 591-92); *see also In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 775 (5th Cir. 2018).

“The manufacturer’s duty to warn is limited to adequately informing the healthcare provider of any risks associated with the product’s use.” *Norplant*, 215 F. Supp. at 803; *see also Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 157 (Tex. 2012) (noting that manufacturers fulfill this duty “by providing adequate warnings to the intermediaries who prescribe the drug and, once fulfilled, [the manufacturer] has no further duty to warn the end users directly”). The adequacy of a warning is a question of fact, and the pleadings must affirmatively establish a warning’s inadequacy to state a plausible claim for relief. *Hale v. Metrex Rsch. Corp.*, 963 F.3d 424, 428 (5th Cir. 2020). However, if the pleadings reference a warning that explicitly warns of the risk which gave rise to the plaintiff’s cause of action, the resulting failure-to-warn claim is insufficient as a matter of law and cannot survive a Rule 12(b)(6) motion to dismiss. *Id.*

#### **E. Breach of Warranty Standards**

Chapter 2 of the Texas Uniform Commercial Code (“UCC”) applies to “transactions in goods[,]” which are defined as “all things . . . which are movable at the time of identification to the contract for sale other than the money in which the price is to be paid, investment securities [], and things in action.” Tex. Bus. & Com. Code Ann. §§ 2.102, 2.105. The UCC provides remedies for buyers and sellers wronged during a transaction for goods. *Id.* §§ 2.702-2.706. For claims involving a warranty in goods, whether express or implied, the UCC governs. *Id.* §§ 2.313-2.314.

“The UCC allows manufacturers to restrict their liability by the exclusion or modification of both implied and express warranties.” *Hou-Tex, Inc. v. Landmark Graphics*, 26 S.W.3d 103, 110 (Tex. App.—Houston [14th Dist.] 2000, no pet.). While there is no specific statutory formula for warranty disclaimers, Texas law imposes a conspicuousness requirement on language that seeks to disclaim implied warranties. *Womco, Inc. v. Navistar Int'l Corp.*, 84 S.W.3d 272, 279 (Tex. App.—Tyler 2002, no pet.). Additionally, the implied warranty of merchantability cannot be disclaimed unless the disclaiming language specifically says “merchantability.” Tex. Bus. & Com. Code Ann. § 2.316(b). If valid, warranty disclaimers travel with goods through subsequent transactions, so “a downstream purchaser cannot obtain a greater warranty than that given to the original purchaser.” *MAN Engines & Components, Inc. v. Shows*, 434 S.W.3d 132, 140 (Tex. 2014). “Words or conduct relevant to the creation of an express warranty and words or conduct tending to negate or limit warranty shall be construed wherever reasonably as consistent with each other . . .” Tex. Bus. & Com. Code Ann. § 2.316.

Absent disclaiming language, Texas law requires six showings to plead a breach of warranty claim:

- (1) the defendant sold [goods or] services to the plaintiff; (2) the defendant made a representation to the plaintiff about the characteristics of the [goods

or] services; (3) the representation became part of the basis of the bargain; (4) the defendant breached the warranty; (5) the plaintiff notified the defendant of the breach; and (6) the plaintiff suffered injury.

*Paragon Gen. Contractors, Inc. v. Larco Constr., Inc.*, 227 S.W.3d 876, 886 (Tex. App.—Dallas 2007, no pet.) (referencing Tex. Bus. & Com. Code Ann. §§ 2.313(a), 2.607(c)(1)).

### III. ANALYSIS

#### A. Burch alleges a plausible design defect claim.

At the Rule 12(b)(6) stage, all Burch must do is plead sufficient “factual content [to allow] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 570). To state a design defect claim under Texas law, a plaintiff must plead that “(1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury.” *Timpke*, 286 S.W.3d at 311. Because Burch’s pleadings set forth sufficient facts to allow the Court to infer those factors, Burch satisfies his pleading burden.

The first *Timpke* prong requires Burch to show “the product was defectively designed so as to render it unreasonably dangerous.” *Id.* KLS argues Burch does not, and indeed cannot, meet this requirement. *See* ECF Nos. 18 at 13-14; 21 at 4. But the Amended Complaint alleged “everyday light activity or events can and do cause [the] thoracic plating systems to flex, weaken, and fracture,” and thus “render[] it unreasonably dangerous.” ECF No. 13 at 5, 7. Federal Rule of Civil Procedure 8 requires a “short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). Burch clears that bar because he pleads specific factual allegations upon which his legal claims are based and provides enough facts to “raise a right to relief above the speculative level.” *See Twombly*, 550 U.S. at 555.

To determine whether a plaintiff has alleged “unreasonable dangerousness” under the first *Timp te* prong, courts look to the five factors listed above. *Hernandez*, 2 S.W.3d at 256 (quoting *Amer. Tobacco Corp.*, 951 S.W.2d at 432). For factor one, medical devices have a high social utility against which their risks must be weighed, meaning plaintiffs like Burch must establish, in light of the remaining factors, that the product was “unreasonably dangerous” even considering the high value it provides for society. Burch’s pleadings accomplish as much.

Burch satisfies factor two by alleging “[a] safer alternative design existed at the relevant time (*i.e.*, a more robust version of the thoracic plating system).” ECF No. 13 at 5. He meets factor three by alleging “[a] more robust design was economically and technologically feasible at the time the thoracic plating system left KLS’[s] control by the application of existing or reasonably achievable scientific knowledge.” *Id.* He fulfills the fourth factor by alleging “[t]he KLS thoracic plating system was more dangerous than an ordinary consumer would expect when it is used in an intended or reasonably foreseeable manner.” *Id.* Finally, he satisfies factor five by asserting that most consumers would expect similar devices to “withstand the ordinary and expected forces of everyday life . . . like breathing, sneezing, [or] coughing.” *Id.* Thus, Burch adequately pleads “unreasonable dangerousness” and passes the first *Timp te* prong.

The second *Timp te* prong requires Burch to allege that a safer alternative design existed that KLS could realistically have designed and produced. *Timp te*, 286 S.W.3d at 311. Although Burch does not provide technical information to support his assertion that such an alternative existed, KLS does not provide facts negating that inference. Because the defect alleged is a “weakness” in the current design, rather than a significant functional limitation, a theoretically superior design would not necessitate sweeping technological innovations, but rather, a more robust variation of the same model. In the absence of contravening facts, the Court must review

Burch's pleadings "in the light most favorable" to his position. *Yumilicious Franchise, LLC*, 819 F.3d at 174. Thus, without facts showing the impracticability of a stronger design, Burch satisfies the second *Timp*te prong. To require a heightened showing at this stage would preclude anyone without an engineering or technological background from ever bringing a design defect claim.

KLS argues Burch's pleadings do not establish that a defective design in the plate was the proximate producing cause of Burch's injuries. ECF No. 18 at 22. KLS asserts that "[b]ecause Plaintiff's allegations of design defect are both implausible and demonstrably false, Plaintiff has failed to allege facts from which this Court can reasonably infer that the rib plate was defectively designed or that the alleged defect was a producing cause of Plaintiff's alleged injuries . . ." ECF No. 18 at 14. But Burch alleged the plate was defectively designed, was not strong enough to withstand normal daily activities, and "the defective design resulted in the fracture . . . which was a producing cause of Plaintiff's injury." ECF No. 13 at 5-6. That assertion satisfies his burden at this stage, because complaints do not need "detailed factual allegations" to survive Rule 12(b)(6) motions to dismiss. *Twombly*, 550 U.S. at 555. Rather, complaints survive Rule 12(b)(6) motions by raising "a right to relief above the speculative level." *Id.*

While Burch ultimately must prove each *Timp*te prong by a preponderance of the evidence, that is the requirement to prevail at trial, not the baseline requirement to state a claim. *Timp*te, 286 S.W.3d at 311. Thus, KLS's arguments would fail at this stage even if meritorious, because "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable and that a recovery is very remote and unlikely." *Twombly*, 550 U.S. at 556 (citation omitted); *see also Neitzke*, 490 U.S. at 327 ("Rule 12(b)(6) does not countenance . . . dismissals based on a judge's disbelief of a complaint's factual allegations."). Accordingly, Chief Judge Lynn should deny KLS's Motion to Dismiss Burch's design defect claim, count one of the Amended

Complaint. ECF No. 13 at 5.

**B. Burch alleges a plausible manufacturing defect claim.**

Burch alleges that when the plate left KLS, it “[p]ossessed a manufacturing defect which rendered it unreasonably dangerous” and “caused it to fracture under ordinary and expected conditions of use about 90 days after its implementation.” ECF No. 13 at 8. KLS responded that “[t]o state a manufacturing defect claim under Texas law, a plaintiff must show ‘a manufacturing flaw which renders the product unreasonably dangerous; that the defect existed at the time the product left the seller, and that the defect was the producing cause of the plaintiff’s injuries.’” ECF No. 18 at 14 (quoting *Gerber v. Hoffman-La Roche, Inc.*, 392 F. Supp. 2d 907, 922 (S.D. Tex. 2005)). The change of a single word between KLS’s Motion and the *Gerber* case defeats that argument. KLS argues the above elements are necessary “to *state* a manufacturing claim under Texas law . . . .” *Id.* (emphasis added). But the case it cites for that proposition provides that the enumerated elements are necessary to “*recover* for a manufacturing defect.” *Gerber*, 392 F. Supp. 2d at 922 (emphasis added). To prevail on his claims at trial or survive a motion for summary judgment, Burch will have to prove the thoracic plate “was defective when it left the hands of the manufacturer and that the defect was a producing cause of [his] injuries.” *Torrington Co.*, 46 S.W.3d at 844. However, to survive a Rule 12(b)(6) motion he need only present “a short and plain statement” showing he “is entitled to relief.” Fed. R. Civ. P. 8(a).

No plaintiff could successfully allege a manufacturing defect as framed by KLS, because “a manufacturing defect exists when a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous.” *Ridgway*, 135 S.W.3d at 600. Yet KLS insists its manufacturing processes are protected trade secrets and that Burch’s discovery requests “put the cart before the horse.” ECF No. 18 at 4. How a plaintiff

could prove a deviation from a product's manufacturing plan without access to that plan is a mystery unanswered in KLS's pleadings. However, the Court need not address discovery issues and summary judgment arguments when reviewing a Rule 12(b)(6) motion to dismiss. District courts "can grant a motion to dismiss only if it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim that would entitle him to relief." *Scanlan*, 343 F.3d at 536. As for his defective manufacturing case, it is possible Burch could prove a "set of facts in support of his claim that would entitle him to relief" following additional discovery. *Id.* Accordingly, dismissal under Rule 12(b)(6) would be improper, and Chief Judge Lynn should deny KLS's Motion to Dismiss for Burch's manufacturing defect claim, count three of the Amended Complaint. ECF No. 13 at 8.

**C. Burch does not allege a plausible failure to warn claim.**

The learned intermediary doctrine excuses medical manufacturers "from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers." *Porterfield*, 183 F.3d at 467-68 (citing *Alm*, 717 S.W.2d at 591-92). Burch concedes his surgeon chose to use KLS's plate in Burch's surgery. ECF No. 13 at 8. Thus, the decision on which device to use was not primarily Burch's, and the learned intermediary doctrine applies. *Reyes*, 498 F.2d at 1276. Therefore, Burch must make two showings to allege a viable claim: (1) KLS failed to adequately warn his surgeon, Dr. Mohamed, of the plate's risks; and (2) that failure was the producing cause of Burch's injuries. *See Medrano*, 28 S.W.3d 87 at 94. These are essential showings for Burch, not an affirmative defense for KLS. *See Centocor*, 372 S.W.3d at 164.

The "adequacy" element is key to the first showing. Burch argues that KLS's "Information for Use" ("IFU") was inadequate and "deprived [his] treating surgeon . . . of information necessary

to understand the thoracic plate system's limitations, to decide if its implantation was appropriate to Plaintiff's lifestyle and employment circumstances, and to obtain valid informed consent from Plaintiff." ECF No. 13 at 8. Thus, Burch argues "Dr. Mohamed was not a 'learned intermediary' and KLS failed to warn the Plaintiff." *Id.*

But this confuses the doctrine's applicability with the adequacy prong from *Medrano*, which is not an exception to the doctrine but a consideration under it. The doctrine unquestionably applies here on the facts pleaded by Burch. *See Reyes*, 498 F.2d at 1276; *Porterfield*, 183 F.3d at 467-68. However, even where the doctrine applies, plaintiffs still can argue the provided warning was inadequate, and thus the doctrine does not bar their claim. But the very facts alleged in Burch's pleadings to demonstrate the warning's inadequacy undermine his argument. Even the selective quotes Burch chooses from the IFU suffice as "adequate warnings" for the plate under Texas law.

In relevant part, Burch quotes the IFU as stating:

[T]he device can break or bend as a result of stress, activity, weight-bearing[,] or load-bearing . . . If healing is delayed or does not occur, the implant could eventually break due to metal fatigue. Loads produced by weight bearing and activity levels will dictate the longevity of the implant . . . [P]hysical activity and full weight-bearing or load-bearing have been implicated in premature loosening, migration, bending or fracture of internal fixation devices . . . and [the device] may fracture, in the absence of complete bone healing, under normal weight-bearing or load-bearing.

ECF No. 13 at 7-8. Burch alleges a fateful sneeze in June 2019 fractured the plate and caused his injuries. *Id.* at 3. But as Burch notes, the IFU warns "the device can break or bend as a result of stress, activity, weight-bearing[,] or load-bearing," and further cautions that "[i]f healing is delayed or does not occur, the implant could eventually break due to metal fatigue. Loads produced by weight bearing and activity levels will dictate the longevity of the implant." *Id.* at 7. The IFU also warns that "in the absence of complete bone healing" the device may fracture "under normal weight-bearing or load-bearing" conditions. *Id.* By its very terms, that language put Burch on

notice, through Dr. Mohamed as a learned intermediary, that everyday activities and “normal weight-bearing” might cause fracturing absent complete bone healing. Under Texas law, when the pleadings reference a warning that specifically warns of the risk from which the Complaint arises, as the above language here does, they are insufficient as a matter of law and cannot survive a motion to dismiss under Rule 12(b)(6). *Hale*, 963 F.3d at 428.

Burch contends “no meaningful definition of ‘stress, activity, weight-bearing, or load-bearing’ is provided in the IFU.” *Id.* But KLS’s duty is to warn the physician of known dangers, and the physician is responsible for advising patients accordingly. *See Norplant*, 215 F. Supp. at 797 (“[T]he prescribing physician [] acts as a ‘learned intermediary’ between the manufacturer and the ultimate consumer and assumes responsibility for advising individual patients of the risks associated with the [device].”). To require more from manufacturers would ask for clairvoyance such that they could anticipate every conceivable manifestation of the articulated risk for every patient. That is a demand the law does not make. *Id.*

The IFU articulated the risks of KLS’s thoracic plate. Thus, Burch cannot establish in his pleadings that “but for the inadequate warning, [his] doctor would have recommended different treatment or provided additional warnings” such that he would not have consented to its use in his surgery. *See In re DePuy Orthopaedics, Inc.*, 888 F.3d at 775. Because Burch cannot establish that KLS inadequately warned his surgeon, he fails to make the first showing *Medrano* requires. *See Medrano*, 28 S.W.3d 87 at 94.

Because Burch’s pleadings do not establish the first requirement under *Medrano*, the analysis need not progress to the second issue regarding a causal connection between the inadequate warning and his injuries. Nevertheless, the undersigned will briefly address the causality issue with respect to KLS’s warning and Burch’s alleged injuries, because the law

requires plaintiffs “show *both* that the warning was defective and that it was the producing cause of the plaintiff’s injury.” *Medrano*, 28 S.W.3d at 94 (emphasis added). Burch’s Complaint does not specify what particular warnings could or should have been given that would have materially altered his choice to consent to surgery with the KLS plate. *See* ECF No. 13 at 7-8. Rather, the only reference that hints at a causal connection between KLS’s failure to warn and Burch’s alleged injuries is a conclusional recitation of the elements of the underlying cause of action. In relevant part, the Amended Complaint states:

The IFU’s vague use information resulted in a failure to properly warn Dr. Mohamed, and was a direct and proximate producing cause of the personal injury for which Plaintiff seeks recovery. But for this inadequate warning, Dr. Mohamed would have recommended different treatment, or selected a different device, or would have given Plaintiff advice that would have lead him to withhold consent.

*Id.* at 8.

Without more facts to substantiate that allegation, such an assertion is a “threadbare recitation” incapable of surviving a Rule 12(b)(6) motion to dismiss. *See Iqbal*, 556 U.S. at 678. But as stated above, the analysis does not have to progress that far, as both Texas courts and the Fifth Circuit have held that plaintiffs like Burch must show the inadequacy of a warning in their pleadings to state a plausible claim for relief. *Hale*, 963 F.3d at 428. If the pleadings reference a warning that expressly warns of the risk or type of risk that gave rise to the plaintiff’s injuries, the complaint cannot survive a Rule 12(b)(6) motion to dismiss. *Id.* Accordingly, Chief Judge Lynn should grant KLS’s Motion to Dismiss Burch’s failure to warn claim, count two of the Amended Complaint. ECF No. 13 at 6.

**D. Burch does not allege plausible claims for breach of express or implied warranties.**

Burch maintains that KLS’s statements regarding the device were “false, misleading, and inaccurate in that the rib plate product was unsafe, unreasonably dangerous, improper, not of

merchantable quality, and defective,” and that he thus has a breach of warranty claim as a “downstream purchaser of goods.” *See* ECF No. 13 at 10-12. But Burch cites no legal authorities for that self-classification. The Amended Complaint admits “[i]t is unknown to Plaintiff, a ‘downstream purchaser of goods,’ who initially purchased the foregoing medical devices from KLS (e.g., United Regional Health Care Center, Dr. Mohamed, or an unknown third party) . . . .” *Id.* at 3. Inherent in the idea of a “downstream purchaser” is an “upstream purchaser” from whom the individual purchased goods. That Burch does not know who purchased the plate undermines his self-classification as a downstream purchaser. He cannot claim to be party to a “transaction in goods” if he never chose the goods or participated in the transaction.

Rule 12(b)(6) dismissals are appropriate when a party fails to establish a claim’s essential elements on the face of their pleadings. *Yumilicious Franchise, LLC*, 819 F.3d at 174 (quoting *Twombly*, 550 U.S. at 570). As noted above, a plaintiff must allege six items to assert a breach of warranty claim. *Paragon Gen. Contractors, Inc.*, 227 S.W.3d at 886 (referencing Tex. Bus. & Com. Code Ann. §§ 2.313(a), 2.607(c)(1)). Before progressing to an analysis of KLS’s disclaimers, it is evident Burch cannot make three of the necessary showings: that KLS “sold [goods or] services to [him]”; (2) [KLS] “made a representation to [him] about the characteristics of the [goods or] services”; and (3) “the representation became part of the basis of the bargain.” *Id.*

Burch does not make showing one because his pleadings do not state that KLS sold the plate to him or that he had any transaction involving the plate other than in agreeing to the surgery that Dr. Mohamad performed. ECF No. 18 at 8. Burch does not make showing two because even if KLS made representations about the plate, Burch concedes it was Dr. Mohamad, rather than Burch, who decided which plates to use in the surgery. ECF No. 13 at 8. Burch therefore cannot

establish showing three because no representation by KLS induced the agreement between Burch and Dr. Mohamad for his surgery. *Id.* Consequently, Burch has not pleaded a *prima facie* claim for breach of warranty and his case is subject to dismissal under Rule 12(b)(6). *Jones*, 549 U.S. at 215.

Even if Burch's allegations were true *and* he were a downstream purchaser of the plate, he still would not have a colorable breach of warranty claim. The only sale of goods alleged in this matter was KLS's sale of the device to Burch's medical provider. ECF No. 18 at 8. In that sale, KLS disclaimed the very express warranties Burch asserts. *Id.* KLS's Sales Policy & Terms & Conditions ("T&C") states "**[t]his Warranty does not extend to any party other than the Buyer.**" *See* ECF No. 18-2 (Ex. B). The same preclusion applies to Burch's implied warranty claim, as the T&C further states:

**[t]he stated express Warranties are the sole Warranties applicable to the Goods and are in lieu of all other warranties, express or implied, written or oral, including, without limitation, the implied warranty of merchantability, the implied warranty of fitness for a particular purpose and the implied warranty of non-infringement. All such implied warranties are expressly disclaimed by [KLS].**

ECF No. 18-2 (Ex. B). The above-quoted language was separated from surrounding font and bolded in the T&C, thus satisfying Texas law's conspicuousness requirement for implied warranty disclaimers. *Womco, Inc.*, 84 S.W.3d at 279. It also satisfies the UCC's requirement that disclaimers of the implied warranty of merchantability specifically say "merchantability." Tex. Bus. & Com. Code Ann. § 2.316(b). Thus, the disclaimer was facially proper and "traveled" with the device through subsequent transactions. *MAN Engines*, 434 S.W.3d at 140.

Moreover, if Burch had stated facts that could be construed as expanding KLS's warranty beyond the boundaries that disclaimer contemplates, "[w]ords or conduct relevant to the creation of an express warranty and words or conduct tending to negate or limit warranty shall be construed wherever reasonable as consistent with each other." Tex. Bus. & Com. Code Ann. § 2.316. Burch

alleged no facts that contradict this disclaimer. Furthermore, Burch seeks an implied warranty the original purchaser never had. This precludes his implied warranty claim, because “a downstream purchaser cannot obtain a greater warranty than that given to the original purchaser.” *MAN Engines*, 434 S.W.3d at 140.

Courts narrowly constrain their Rule 12(b)(6) analysis to the pleadings and any documents referenced in the pleadings. *Twombly*, 550 U.S. at 555-57. Burch specifically references the T&C, thus directing the Court’s attention to clear disclaimers of the warranties his pleadings assert. The Supreme Court has observed that complaints may be dismissed under Rule 12(b)(6) if “the allegations, taken as true, show the plaintiff is not entitled to relief.” *Jones*, 549 U.S. at 215. The same is true for pleadings and any documents referenced in the pleadings, such as the T&C at issue here. The T&C disclaims the warranties Burch’s pleadings assert, thus demonstrating Burch “is not entitled to relief.” *Id.*

Because Burch’s Amended Complaint and the documents it references show he is not entitled to relief, his case is subject to dismissal under Rule 12(b)(6). Thus, Burch cannot state a viable claim for relief for breach of warranty. The disclaimer contained in the T&C referenced in the Amended Complaint disclaims any warranty liability KLS otherwise might have. Therefore, Chief Judge Lynn should grant KLS’s motion to dismiss Burch’s claims for breach of express and implied warranties, counts four and five of the Amended Complaint. ECF No. 13 at 9.

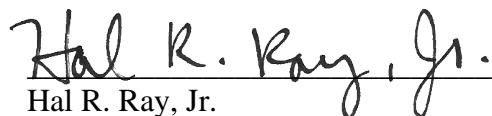
#### IV. CONCLUSION

The undersigned **RECOMMENDS** that Chief Judge Lynn **GRANT in part** and **DENY in part** Defendant KLS Martin, LP’s Motion to Dismiss. ECF No. 18. Chief Judge Lynn should **DISMISS** Burch’s failure to warn and breach of warranty claims, counts two, four, and five of the Amended Complaint, respectively, because they fail to state a claim on which relief can be granted.

Chief Judge Lynn should **NOT DISMISS** Burch's design and manufacturing defect claims, counts one and three of the Amended Complaint, respectively, because dismissal under Rule 12(b)(6) is improper.

A copy of these findings, conclusions, and recommendation shall be served on all parties in the manner provided by law. Any party who objects to any part of these findings, conclusions, and recommendation must file specific written objections within 14 days after being served with a copy. *See* 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b)(2). In order to be specific, an objection must identify the particular finding or recommendation to which objection is made, state the basis for the objection, and specify the place in the magistrate judge's findings, conclusions, and recommendation where the disputed determination is found. An objection that merely incorporates by reference or refers to the briefing before the magistrate judge is not specific. Failure to file specific written objections will bar the aggrieved party from appealing the factual findings and legal conclusions of the magistrate judge that are accepted or adopted by the district court, except upon grounds of plain error. *See Douglass v. United Servs. Auto. Ass'n*, 79 F.3d 1415, 1417 (5th Cir. 1996) (en banc).

**SIGNED** on November 18, 2021.

  
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Hal R. Ray, Jr.  
UNITED STATES MAGISTRATE JUDGE